SPIRALING DRUG COSTS: WHAT CAN STATES DO?

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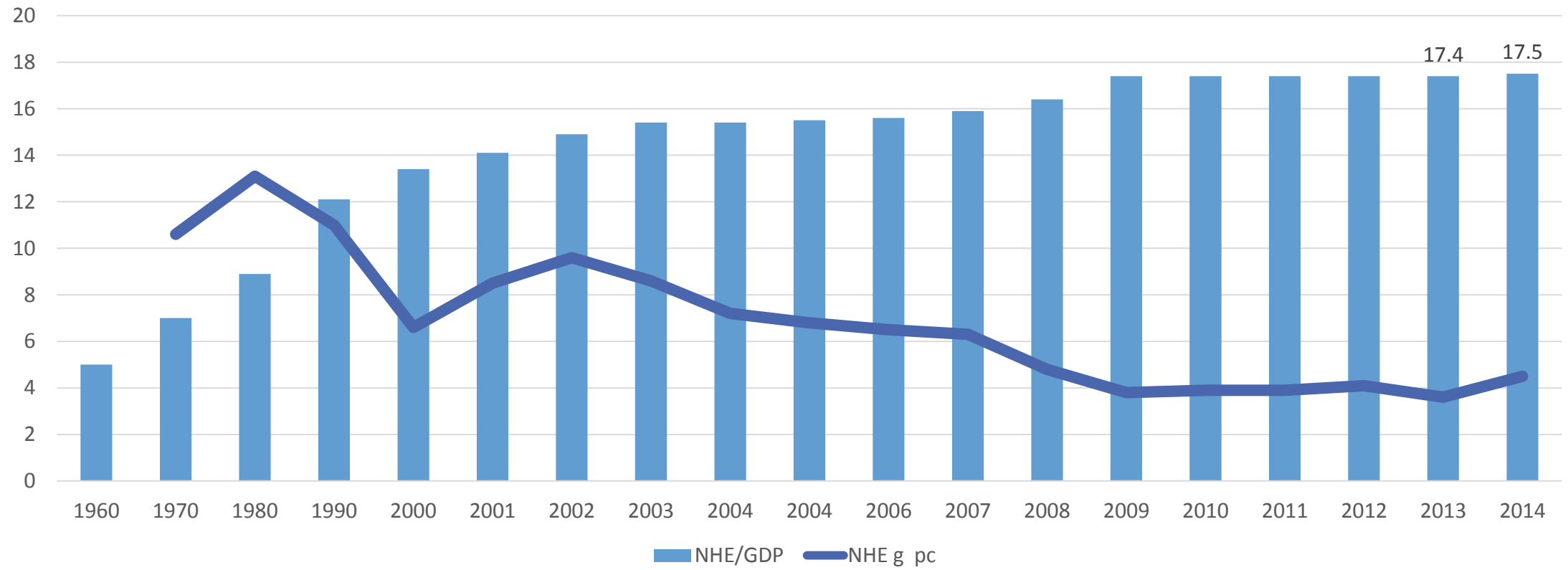
OVERVIEW

- Recent cost growth facts
- The Bargain we have struck with drug manufacturers
- Recent issues with specialty and with generic drugs
- Policy Options

Growth in health spending, share of GDP of health spending



Health Care Prices and Related Statistics: 12-Month Growth Rates

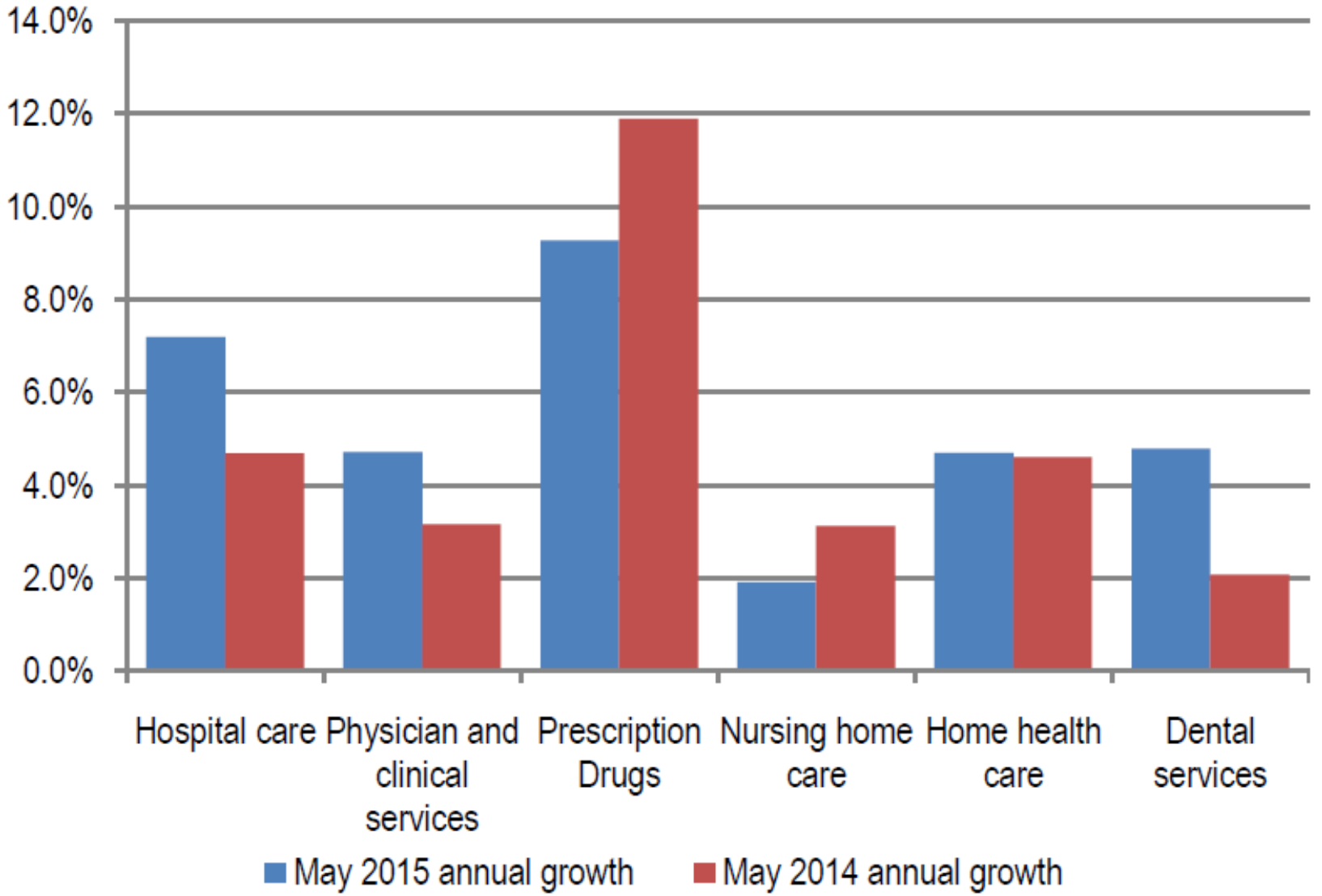
	Oct 2013	Oct 2014	Sep 2015	Oct 2015
Health Care Price Index (HCPI)	1.3%	1.2%	1.0%	1.2%
GDPD	1.3%	1.7%	0.8%	*
HCPI–GDPD	0.0%	-0.5%	0.2%	*
Addendum				
Health care spending	4.%	5.4%	5.5%	5.4%
Health care utilization	2.8%	4.2%	4.5%	4.2%
CPI—medical	2.3%	2.1%	2.5%	3.0%
CPI—all items	1.0%	1.7%	0.0%	0.2%

Source: Altarum Institute analysis of U.S. Bureau of Labor Statistics data. HCPI is a composite price index designed to measure overall price changes for personal health care spending and is patterned after the price index developed by the Centers for Medicare & Medicaid Services (CMS). Details are provided on page 4.

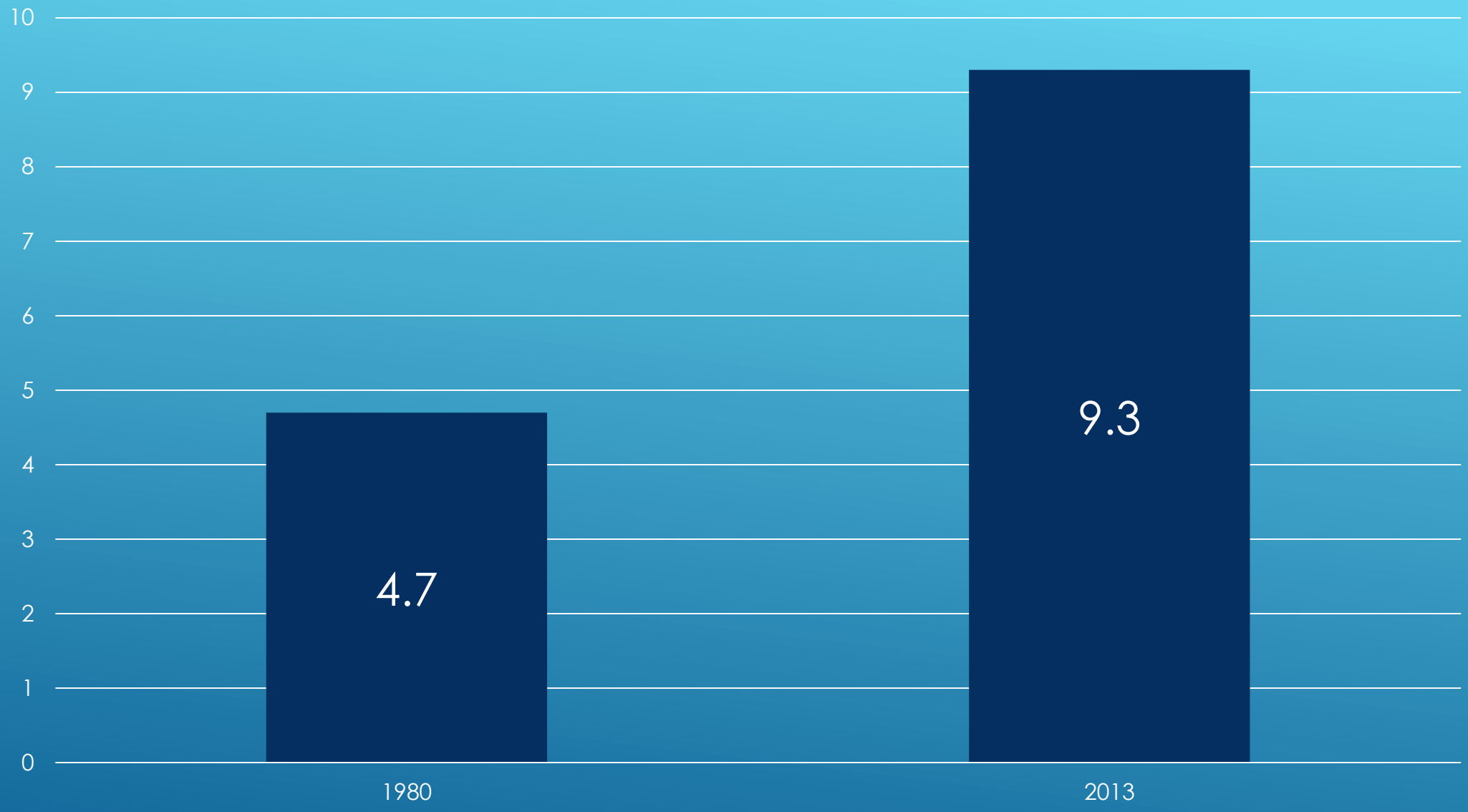
Numbers may not subtract properly due to rounding.

* Data are not yet available.

Exhibit 4. Health Spending Year-over-Year Growth for Selected Categories



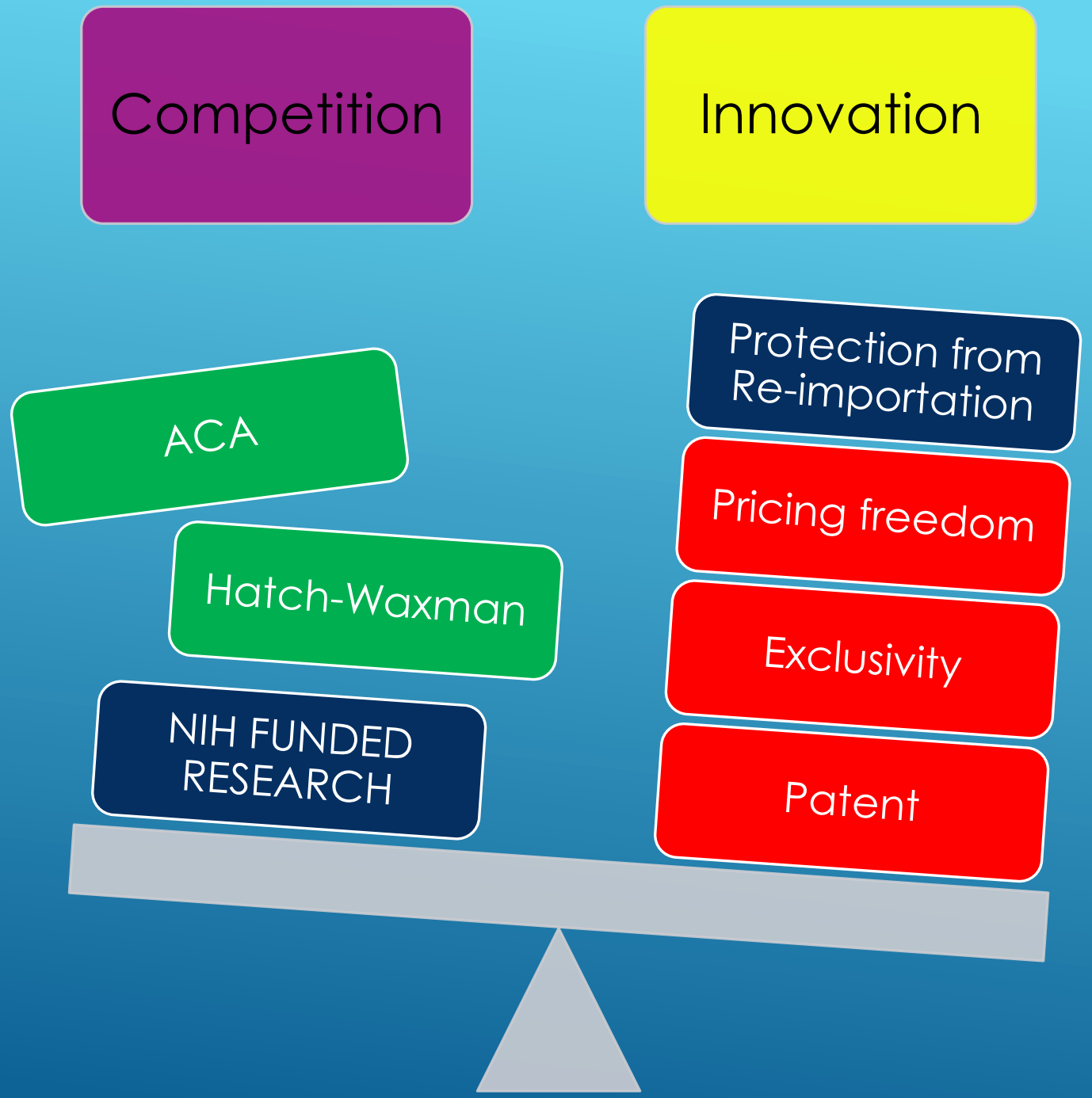
Source: Altarum monthly national health spending estimates.



DRUG SPEND / TOTAL HEALTH SPEND

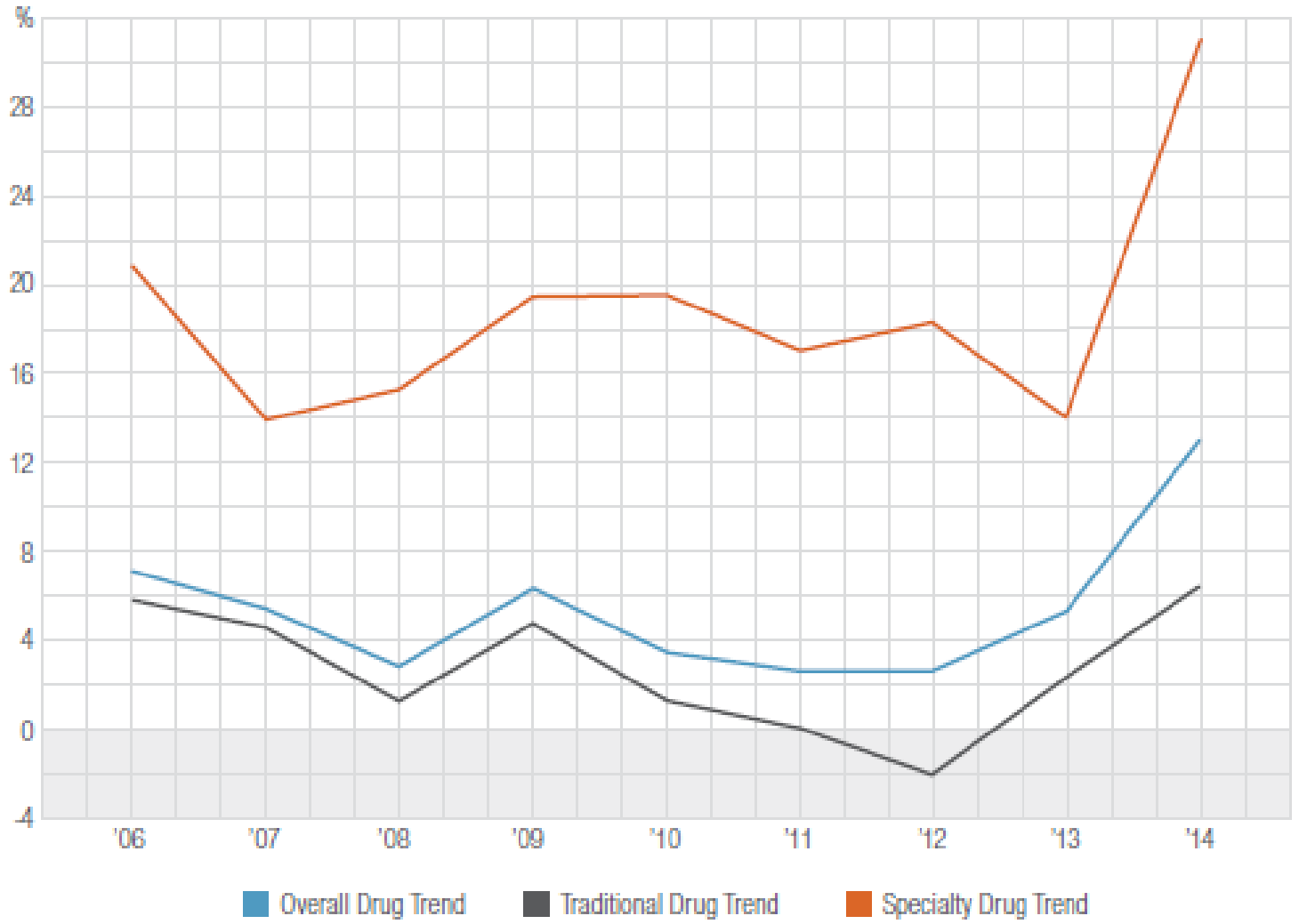
THE BARGAIN WE HAVE STRUCK

- "Fixed Term" monopolies to spur innovation
  - Patents = 20 years (formerly 17)
  - Exclusivities, data and marketing, range from 180 days to 12 years
- Competition from generics or biosimilars after exclusivities of 5 and 12 years, respectively
- 85% of small molecule drugs are generic today
- FDA approved first biosimilar in March 2015, competes with drug first launched in 1991
- Medicaid gets legislated "discounts," Medicare pays retail


Competition
Innovation
ACA
Hatch-Waxman
NIH FUNDED RESEARCH
Protection from Re-importation
Pricing freedom
Exclusivity
Patent

TRADITIONAL, SPECIALTY AND OVERALL TREND

2006 TO 2014



HEP C AS "SPECIAL" CASE

- Sovaldi *cures* Hepatitis C
- Launch price in 2014 was $1000 / pill, $84,000 per episode
- Half of nation's 3.2 Hep C patients are on Medicaid
- Medicaid prescription drug spending rose 23% in 2014

63% Increase in N of patients with more than $50,000 in drug spend from 2013-2014

MAJOR COST DRIVERS

The estimated number of Americans with drug costs exceeding $50,000 increased 63% in 2014, from 352,000 to 576,000. The estimated size of the population at the highest end of this spectrum – **where annual medication costs exceed $100,000 per patient** – jumped 193%, from an estimated 47,388 to 138,722 Americans. This population now represents 6.5% of total U.S. drug spend (up from 2.5% in 2013).

As noted in Table 1 below, the 0.2% of patients with annual spending at or above $50,000 accounted for 16% of total spend, while the costliest 5% of patients accounted for 61% of the country's total medication spend.

TABLE 1: DISTRIBUTION OF PATIENTS

BY COST CATEGORY

COST CATEGORY	% TOTAL PATIENTS		% TOTAL COST	
	% TOTAL	CUMUL. %	% TOTAL	CUMUL. %
≥$100,000	0.05%	0.05%	6.5%	6.5%
$50,000 - $99,999	0.17%	0.22%	9.2%	15.7%
$10,000 - $49,999	1.8%	2.0%	27.6%	43.2%
$5,000 - $9,999	3.1%	5.1%	17.8%	61.0%
$1,000 - $4,999	15.6%	20.7%	29.6%	90.7%
<$1,000	48.2%	68.9%	9.3%	100.0%
NON-UTILIZERS	31.1%	100.0%		
TOTAL	100.0%		100.0%	

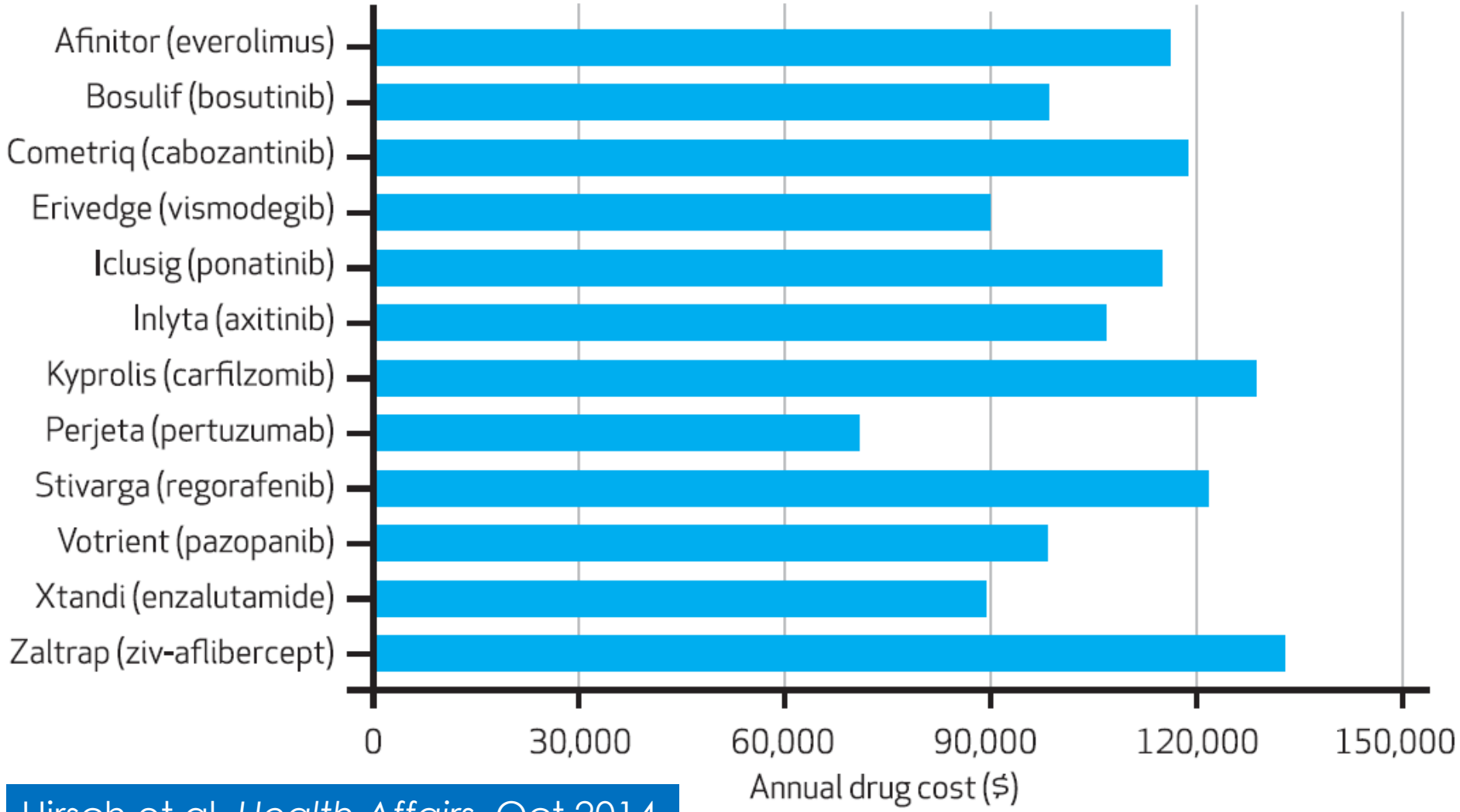
193% Increase in N of patients with more than $100,000 in drug spend from 2013-2014

SOME COST-SHARING FACTS

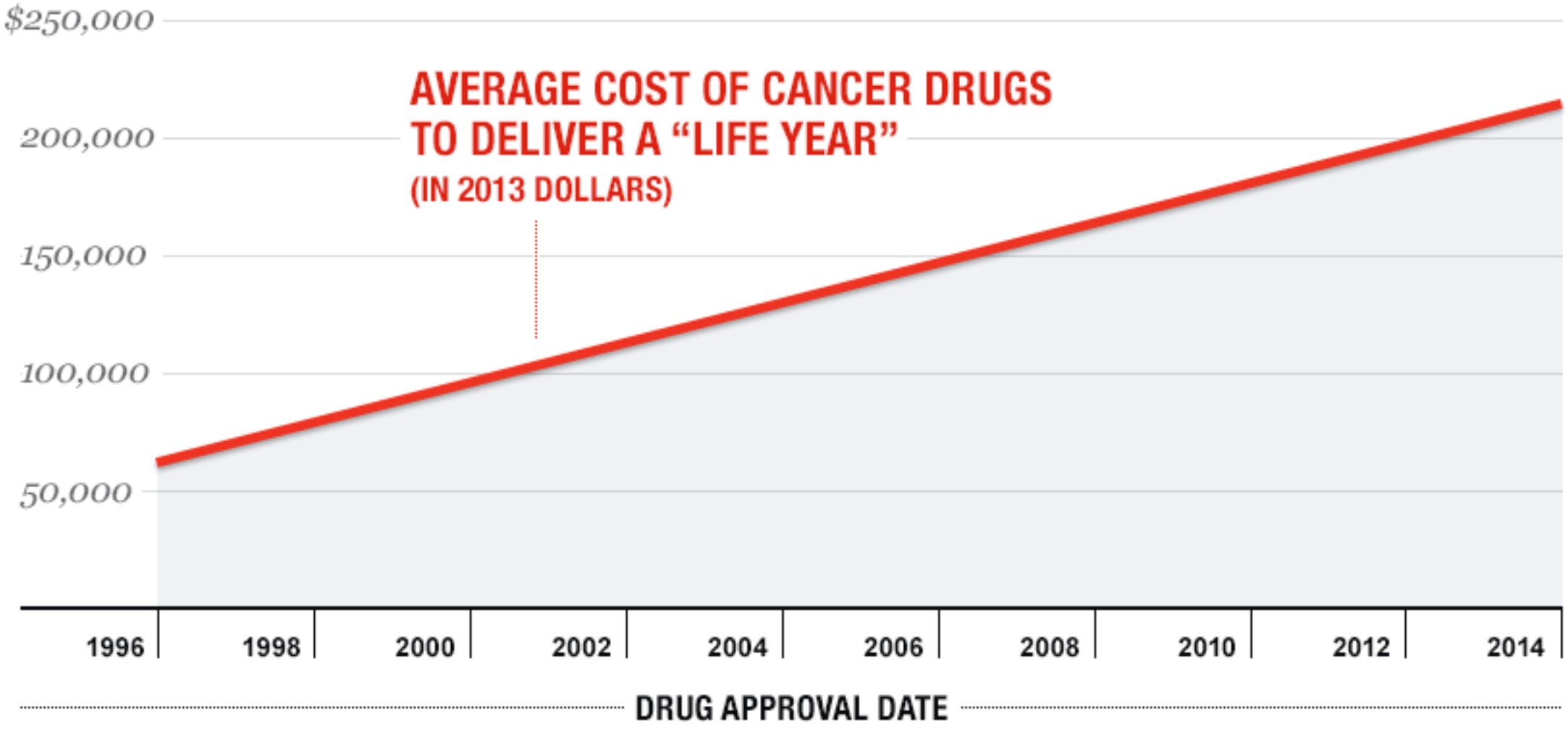
- Part B drugs require 20% coinsurance, there is no OOP cap
  - Average annual income of elderly = $23,000
- Part D is increasingly using coinsurance, with $7000 cap
- Marketplace and employer plans use coinsurance for tiers 3 and 4; average for silver and bronze is 40%, some 60%
- OOP cap for ACA plans is $6,600/$13,200
- ERISA plans have no statutory OOP cap
- One survey (JMCP) found most have 25% coinsurance or more for oral cancer drugs; delays and suspensions common

EXHIBIT 1

Annual Cost Of Oncologic Drugs Approved By The Food And Drug Administration In 2012



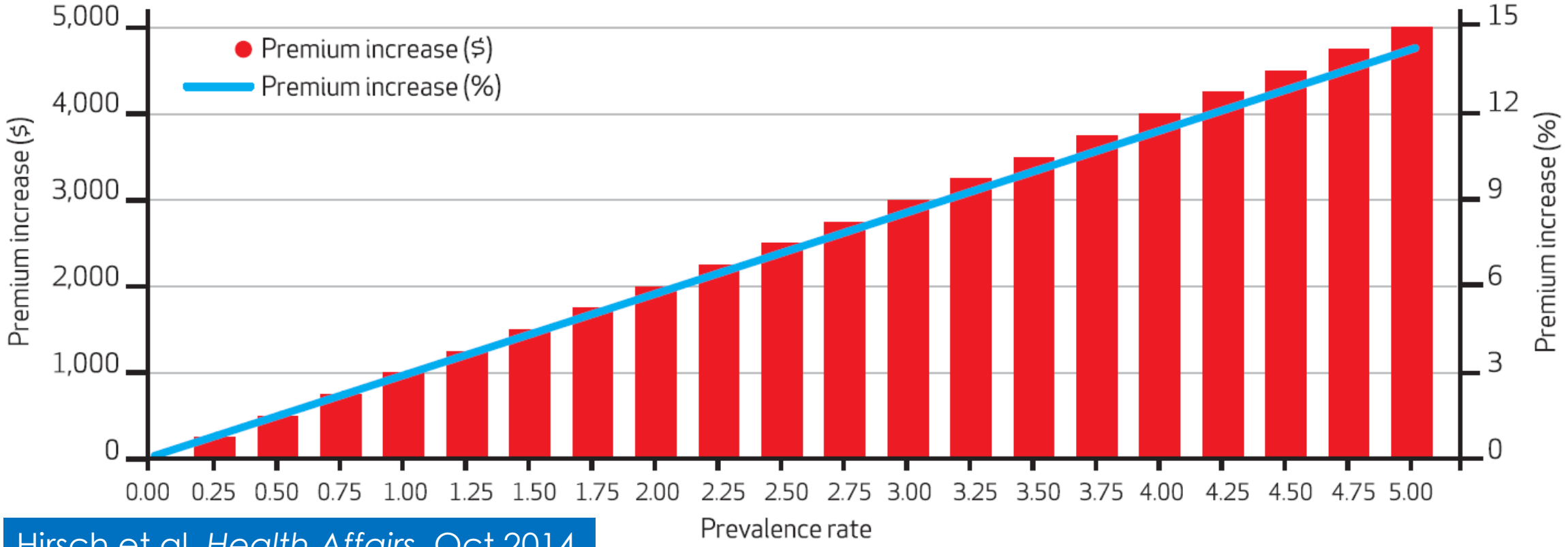
Hirsch et al, *Health Affairs*, Oct 2014



SOURCE: DAVID H. HOWARD, PETER B. BACH, ERNST R. BERNDT, AND RENA M. CONTI, "PRICING IN THE MARKET FOR ANTICANCER DRUGS," *JOURNAL OF ECONOMIC PERSPECTIVES*, 2015

EXHIBIT 2

Rate And Percent Increase In Insurance Premiums For A New Specialty Drug Costing $100,000 Per Treated Patient, Depending On Disease Prevalence



Hirsch et al, *Health Affairs*, Oct 2014

SOURCE Authors' analysis. **NOTES** "Premium increase ($)" (the red bars) denote the absolute increase in premium paid; it relates to the left-hand *y* axis. "Premium increase %" (the blue line) relates to the right-hand *y* axis. For every 1 percent increase in the share of the population using the new drug, overall health care costs would be expected to increase $1,000. See the online Appendix (see Note 10 in text) for information about the derivation of the included values.

Generic prices are a problem TOO

Over 5000% Price Gouge Still Not Lowered by Turing Pharmaceuticals CEO, Martin Shkreli

Announcement to lower the price of Daraprim merely a tactic to placate critics

By **Michael Sainato** | 10/09/15 3:07pm

Observer.com

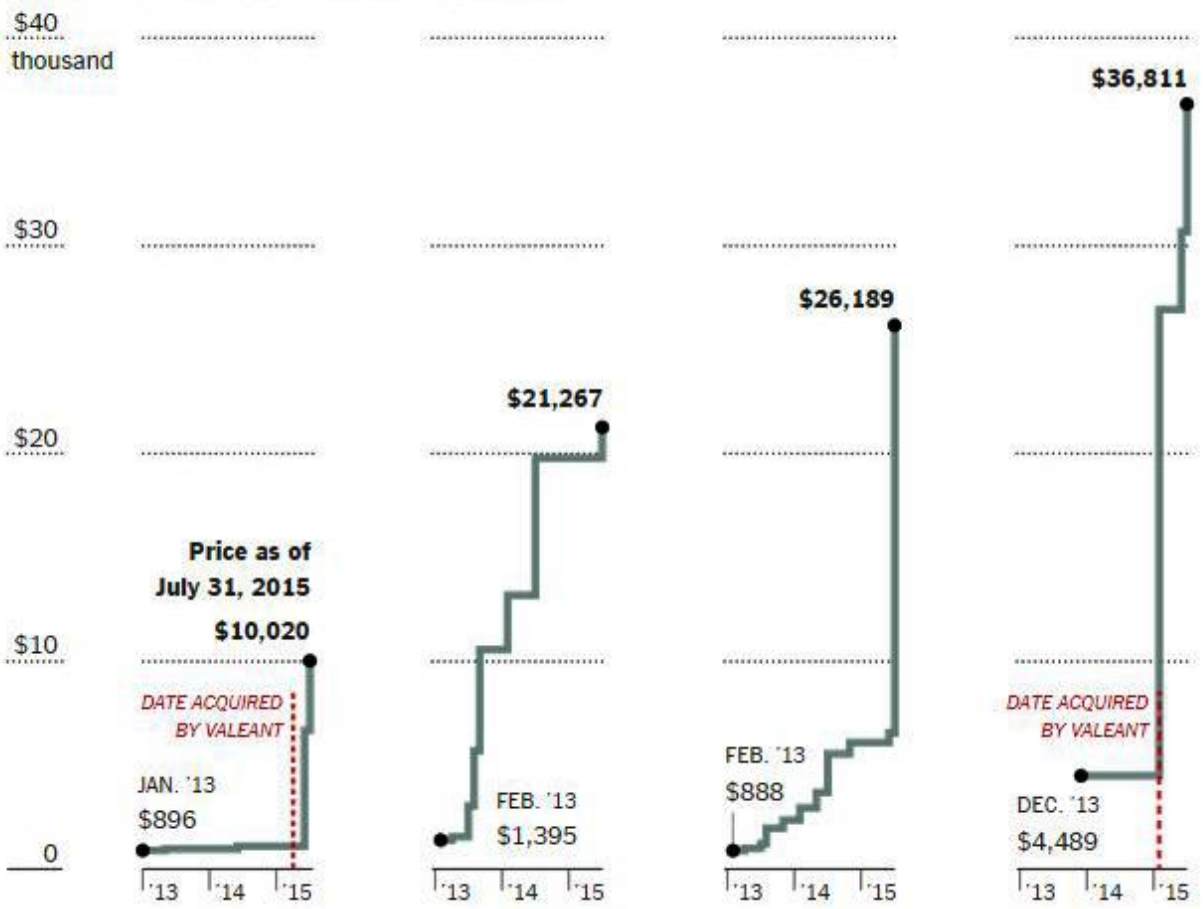
Generic prices are a problem TOO

The New York Times

October 5, 2015

By ANDREW POLLACK and SABRINA TAVERNISE

List prices for some of Valeant's prescription drugs



	Glumetza	Syprine	Cuprimine	Isuprel
DRUG				
AMOUNT	Ninety 1,000 mg tablets	One hundred 250 mg capsules	One hundred 250 mg capsules	Twenty-five 0.2 ml ampules
TREATMENT FOR	*Diabetes*	*Wilson disease*	*Wilson disease*	*Slow or irregular heart rate*

Note: The rights to Syprine, Cuprimine and Demser were acquired by Valeant in 2010.
Source: AB Bernstein

WHY MUST DRUG PRICES BE SO HIGH?

To recover past R&D costs, accounting for time lag

- But those costs are SUNK!!!

- To capture value created – consumer willingness to pay – compared to alternative treatments
  - What about penicillin? Life saving EMTs?
- **To fund current research and marketing plans**
- **To reward investors NOW**

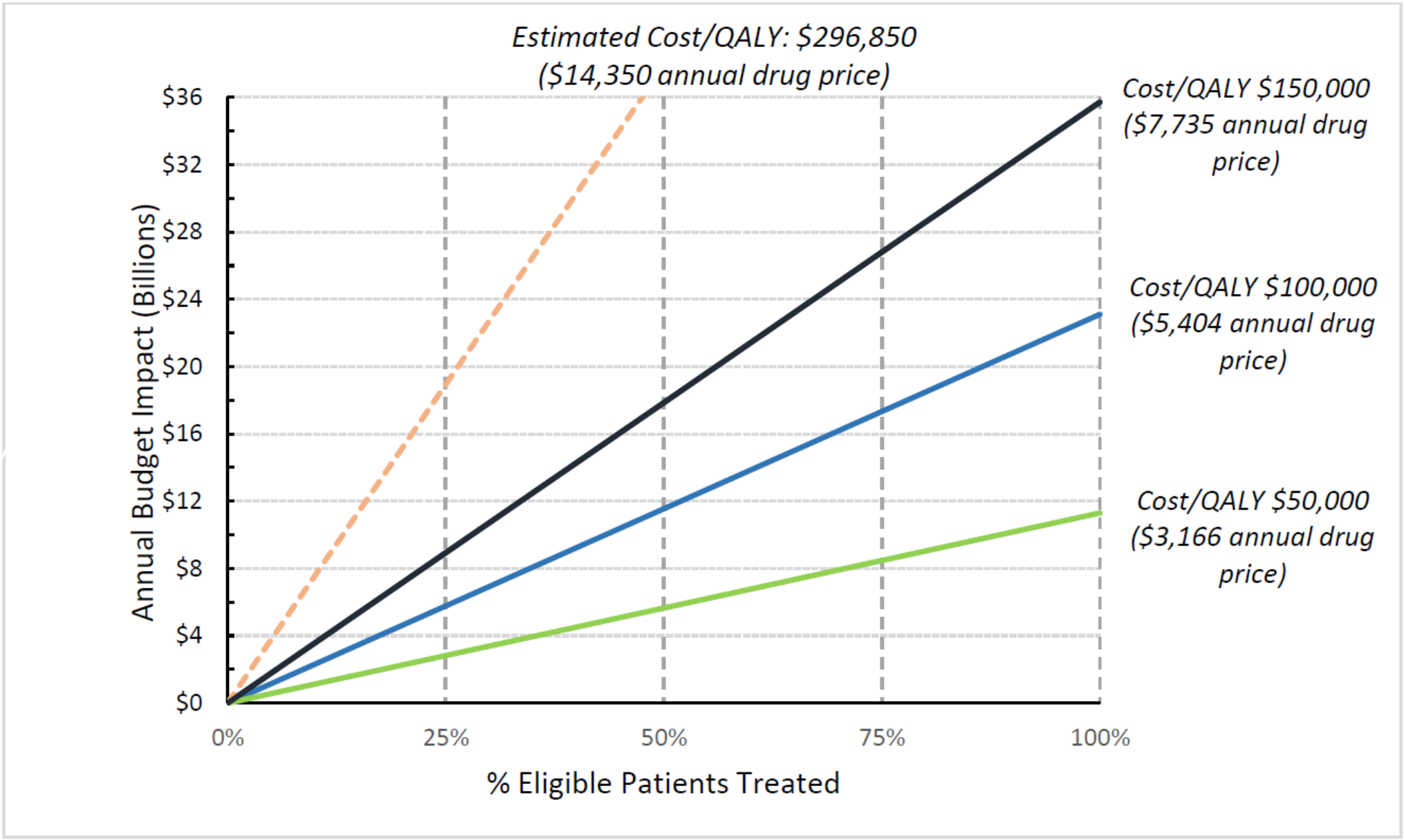
SOME POLICY OPTIONS

- Federal levers
  - Adjust patent and/or exclusivity rules
  - Speed up FDA approval times with resources
  - Give Medicare the power to negotiate prices
  - Dictate lower cost sharing
  - Allow importation
  - Increase price transparency
  - Impose price regulation or require larger discounts

- State levers
  - Require larger discounts through formula adjustment
  - Create multi-agency and multi-state bargaining units and use reference pricing and transparency strategy
  - Enable state to say “no”

Institute for Clinical and Economic Review Estimate of "Value" of PCSK9 inhibitor

ICER-review.org



MAIN TAKEAWAY ON PRICING POLICY OPTIONS

- Drug markets are segmentable, => price discrimination is possible
- Price discrimination is generally both efficient and equitable
- Price discrimination works best when markets are cordoned off
- When you use a formula to "guarantee" discounts, you LINK markets, so formulaic discount will raise optimal price in private markets (340B and Medicaid rules all have this effect)
- **So, using (augmented) market bargaining power is better than formulaic discounts for the state as a whole**

COMMENTS AND QUESTIONS

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